

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 5 1984

OFFICE OF
PESTICIDE AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: 84-OR-08. Proposed Section 18 specific exemption
for the use of vinclozolin on green snap beans in
Oregon.

FROM: Michele L. Loftus, Chemist
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Hazard Evaluation (TS-769) *Michele L. Loftus*

THRU: Charles L. Trichilo, Ph.D., Chief
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TO: Emergency Response Section
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

The Oregon Department of Agriculture requests a Section 18 specific exemption for the use of 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione (vinclozolin), trade name: Ronilan 50W, on green snap beans which does not require the imposition of a restriction against feeding cannery bean waste to livestock.

The proposed use is the same as that reviewed by E. Zager (83-OP-18, 8/4/83). Two applications of Ronilan 50W will be made at the rate of 0.5 lb ai/A with a 9 day PHI. For ground treatments, 40-100 gal water/A will be used. For aerial treatments, a minimum of 15 gal water/A will be used. A restriction against feeding treated snapbeans vines and hay to livestock will be imposed on the Section 18 label. If two treatments are necessary, a maximum of 40,000 lbs ai will be used to treat 20,000 acres of beans.

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The metabolism of vinclozolin in plants was most recently discussed in our review of PP#2F26FO (K.H. Arne, 6/11/82). The residues of concern are the parent 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-methyl-2,4-oxazolidinedione (vinclozolin) and its metabolites containing the 3,5-dichloroaniline moiety.

Permanent tolerances are established (40 CFR §180.380) for vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety in/on kiwifruit, head lettuce, and strawberries at 10 ppm.

Residue data are generated by BASF Method 25 which underwent a successful method tryout in connection with PP#9F2205. The methodology is included in PAM II and is entitled "Gas Liquid Chromatographic Determination of Residues of Vinclozolin and its 3,5-Dichloroaniline-Containing Metabolites in Strawberries and Soil." Briefly, 3,5-dichloroaniline is released from the parent and its metabolites containing this moiety by alkaline hydrolysis and is isolated by steam distillation, partitioned with chloroform for cleanup, derivatized with chloroacetyl chloride and determined by GLC-EC. Reported recoveries from beans fortified with 0.05-5 ppm vinclozolin ranged from 76-86%. Reference standards of vinclozolin are available in the U.S. EPA Pesticides and Chemicals Repository.

Residue data for snapbeans reviewed by E. Zager (4/20/83) in connection with 83-WA-09 reflect 3 studies from Oregon and Idaho. Following 2 applications at the rate of 1 lb ai/A (2x's the proposed use), residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety were 0.42 ppm at a 9 day PHI and 0.24-0.68 ppm at 16-17 day PHI's in/on snap beans and were 5.3 ppm at a 9 day PHI and 4.5-18.8 ppm at 16-17 day PHI's in/on snapbean forage.

Based on the above data, we estimate that residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety will not exceed 1 ppm in/on snapbeans.

Cannery bean waste to be used as feed is comprised of 82-92% (18-24% of gross load) snips, defective pods and spills and 8-18% (2-4% of gross load) vines and leaves which has been thoroughly washed and separated from unuseable product. In our judgement, residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety in cannery bean waste which is used as a feed item will not exceed 1 ppm.

Meat, Milk, Poultry and Eggs

Metabolism and residue studies of vinclozolin in animals has been reviewed by E. Zager (5/11/83) in connection with 83-NC-02. There are no large ruminant metabolism studies available. In a rat metabolism study the major metabolite found in the feces was

N-(3,5-dichlorophenyl)-2-methyl-2,3,4-trihydroxy butenoic acid amide. For the purposes of this Section 18 exemption we consider the residue of concern in animal tissues and milk to consist of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety.

Residue data for animal tissues and milk are generated by a method included in Report III, "Residues of Vinclozolin (BAS 35F) in Milk and Tissues of Dairy Cows" by the Huntington Research Centre, Cambridgeshire, England which was submitted in connection with various Section 18 exemption requests.

The analytical method involves conversion of residues of vinclozolin to dichloroaniline by alkaline hydrolysis, steam distillation, partition into dichloromethane, followed by derivatization with chloroacetyl chloride to N-(3,5-dichlorophenyl)-chloracetamide. This derivative is then determined by gas chromatography with an electron capture detector. The method determines vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety. Reported recoveries from meat and milk fortified with 0.05-2.50 ppm vinclozolin ranged from 77-101%.

In a cattle feeding study two groups of 3 cows each were administered 3 and 15 ppm vinclozolin in the diet for 28 days. Highest residues were found in liver samples up to 0.6 ppm and 2.3 ppm, respectively. Residues in the muscle ranged up to 0.05 ppm and 0.24 ppm, respectively. Residues in the milk were non-detectable (<0.05 ppm) in the cows administered 3 ppm vinclozolin in their diet and ranged up to 0.19 ppm in the group of cows administered 15 ppm in their diet.

Cannery bean waste may comprise up to 20% of the dietary burden of beef and dairy cattle and is equivalent to 0.2 ppm vinclozolin. On the basis of the above feeding studies and the dietary burden, we estimate that secondary residues of vinclozolin and its metabolites containing the 3,5-dichloroaniline moiety will not exceed 0.05 ppm in milk, meat, fat and meat byproducts of cattle, goats, hogs, horses and sheep from this use.

Since cannery bean waste is not a feed item for poultry, there will be no problem of secondary residues in poultry and eggs.

Conclusions

1. The residues of concern in plants and animal tissues and milk are the parent 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione (vinclozolin) and its metabolites containing the 3,5-dichloroaniline moiety.

- 2a. The analytical methodology for determination of residues of the parent 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione (vinclozolin) and its metabolites containing the 3,5-dichloroaniline moiety in plants is Method 25 entitled "Gas Liquid Chromatographic Determination of Residues of Vinclozolin and its 3,5-Dichloroaniline Containing-Metabolites in Strawberries and Soil", included in PAM II.
- 2b. The analytical methodology for determination of residues of the parent 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione (vinclozolin) and its metabolites containing the 3,5-dichloroaniline moiety in animal tissues and milk is included in Report III "Residues of Vinclozolin (BAS 352F) in Milk and Tissues of Dairy Cows" by the Huntington Research Centre, Cambridgeshire, England which was submitted in connection with various Section 18 exemption requests.
- 2c. Reference standards of vinclozolin are available in the U.S. EPA Pesticides and Chemicals Repository.
- 3a. Combined residues of the parent 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione (vinclozolin) and its metabolites containing the 3,5-dichloroaniline moiety will not exceed 1 ppm in/on snap beans as a result of the proposed use.
- 3b. Combined residues of the parent 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione (vinclozolin) and its metabolites containing the 3,5-dichloroaniline moiety will not exceed 1 ppm in cannery bean waste as a result of the proposed use.
- 3c. Secondary residues of the parent 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione (vinclozolin) and its metabolites containing the 3,5-dichloroaniline moiety will not exceed 0.05 ppm in milk, meat, fat and meat byproducts of cattle, goats, hogs, horses and sheep from this use.
- 3d. Since there are no poultry feed items involved in this use, there will be no problem with secondary residues in poultry and eggs.

Recommendation

TOX considerations permitting, we have no objections to the issuance of this Section 18 exemption. An agreement should be made with the FDA and USDA regarding the legal status of the treated commodities in commerce.

TS-769:RCB:M.Loftus:vg:CM#2:RM810:557-7324:6/5/84
 cc: R.P., Circu., M. Loftus, Vinclozolin S.F., Section 18
 RDI: E. Zager, 6/1/84; R. Schmitt, 6/4/84

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